IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appln. No.	:	10/674,296 Confirmation No.: 4107
Appellant	:	THORNTON, Ronan
Filed	:	September 29, 2003
TC/A.U.	:	3738
Examiner	:	PRONE, Christopher
Docket No.	:	P1818
Customer No.	:	28390
Title	:	**LAMINATED DRUG-POLYMER COATED STENT WITH DIPPED AND CURED LAYERS**

APPEAL BRIEF

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313

Dear Sir:

Please consider Appellants' brief as follows:

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1. REAL PARTY IN INTEREST

The real party in interest is Assignee Medtronic Vascular, Inc., a corporation having an office and a place of business at 3576 Unocal Place, Santa Rosa, California 95403.

2. RELATED APPEALS AND INTERFERENCES

Appellants and the undersigned attorney are not aware of any appeals, judicial proceedings, or any interferences that may be related to, directly affect or be directly affected by, or have a bearing on the Board's decision in the pending appeal.

3. STATUS OF CLAIMS

Claims 1-21, 25-31, 35, 37, 38 and 40-47 are pending. Claims 22-24, 32-34, 36 and 39 were cancelled. Claims 1-16 were withdrawn from consideration.

Claims 17-21, 25, 28-38, 40, 41, 43-45 and 47 were rejected under 35 U.S.C. 7103(a) as being unpatentable over Fearnot et al. (Fearnot) in view of Hossainy et al. (Hossainy).

Claims 26 and 27 were rejected under 35 U.S.C. 103 as being unpatentable over Fearnot in view of Hossainy and further in view of Guruwaiya et al. (Guruwaiya).

Claims 42 and 46 were rejected under 35 U.S.C. 103 as being unpatentable over Fearnot in view of Hossainy and further in view of Helmus et al. (Helmus).

Claims 17-21, 25-31, 35, 37, 38 and 40-47 are the claims on appeal.

4. STATUS OF AMENDMENTS

No amendments to the claims were filed subsequent to the Final Rejection mailed on July 7, 2009.

5. SUMMARY OF CLAIMED SUBJECT MATTER

In this Summary of Claimed Subject Matter, all citations are to the specification of United States Patent Application 10/674,296. All citations are illustrative only and additional support for the cited elements may be found elsewhere in the specification

Independent Claim 17

A drug-polymer coated stent (120, 220) comprising a stent framework (130, 230); a laminated drug-polymer coating (140, 240) disposed on the stent framework, the laminated drug-polymer coating including a plurality of thin drug-polymer layers (242, 246), wherein the thin drug-polymer layers include a first therapeutic agent and a cured first polymer, and at least one thin barrier layer (244c) positioned between a first thin drug-polymer layer (242) and a second thin drug-polymer layer (246), wherein the at least one thin barrier layer (244c) includes a cured second polymer, wherein the cured second polymer excludes drug interaction between the first thin drug-polymer layer and the second thin drug-polymer layer adjacent the at least one barrier layer (244c). (See paragraphs [00030], [00032], [00043] and FIGS. 1 and 2c).

Independent Claim 25

A system (100) for treating a vascular condition comprising a catheter (110); and a coated stent (120, 220) coupled to the catheter, the coated stent including a stent framework (130, 230); and a laminated drug-polymer coating (140, 240) disposed on the stent framework, the laminated drug-polymer coating including a plurality of thin drug-polymer layers (242, 246) and at least one thin barrier layer (244c) positioned between a first thin drug-polymer layer (242) and a second thin drug-polymer layer (246), wherein the thin drug-polymer layers include a first therapeutic agent and a cured first polymer and wherein the at least one thin barrier layer (244c) includes a cured second polymer, wherein the cured second polymer excludes drug interaction between the first thin drug-polymer layer and the second thin drug-polymer layer

adjacent the at least one barrier layer (244c). (See paragraphs [00030], [00032], [00043] and FIGS. 1 and 2c).

Independent Claim 35

A method of treating a vascular condition comprising inserting (Block 715) a drug-polymer coated stent (120, 220) within a vessel of a body, the drug-polymer coated stent including a laminated drug-polymer coating (140, 240) having a plurality of thin drug-polymer layers (242, 246) and at least one thin barrier layer (244c) positioned between a first thin drug-polymer layer (242) and a second thin drug-polymer layer (246) one, wherein the thin drug-polymer layers (242, 246) include a first therapeutic agent and a cured first polymer and wherein the at least one thin barrier layer (244c) includes a cured second polymer, wherein the cured second polymer excludes drug interaction between the first thin drug-polymer layer and the second thin drug-polymer layer adjacent the at least one barrier layer (244c); and eluting (Block 720) at least one therapeutic agent from the laminated drug-polymer coating into the body, wherein the first polymer is cured with one of thermal activation, electrical activation, or ionizing irradiation. (See paragraphs [00081] to [00085] and FIGS. 1, 2c and 7).

6. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Whether claims 17-21, 25, 28-38, 40, 41, 43-45 and 47 are patentable over Fearnot et al. (Fearnot) in view of Hossainy et al. (Hossainy).

Whether claims 26 and 27 are patentable over Fearnot in view of Hossainy and further in view of Guruwaiya et al. (Guruwaiya).

Whether claims 42 and 46 are patentable over Fearnot in view of Hossainy and further in view of Helmus et al. (Helmus).

Claims 17-21, 25-31, 35, 37, 38 and 40-47 are the claims on appeal.

7. ARGUMENTS

The Appellants respectfully submit that claims 17-21, 25, 28-38, 40, 41, 43-45 and 47 are patentable over Fearnot in view of Hossainy, that claims 26 and 27 are patentable over Fearnot in view of Hossainy and further in view of Guruwaiya and that claims 42 and 46 are patentable over Fearnot in view of Hossainy and further in view of Helmus. The Appellant further submits that the rejections of claims 17-21, 25-31, 35, 37, 38 and 40-47 should be reversed.

35 U.S.C. §103 Rejection

To maintain a proper rejection under 35 U.S.C. § 103, the Office must meet four conditions to establish a *prima facie* case of obviousness. First, the Office must show that the prior art suggested to those of ordinary skill in the art that they should make the claimed composition or device or carry out the claimed process. Second, the Office must show that the prior art would have provided one of ordinary skill in the art with a reasonable expectation of success. Both the suggestion and the reasonable expectation of success must be adequately founded in the prior art and not in an applicant's disclosure. Third, the prior art must teach or suggest all the claim limitations. *In re Vaeck,* 20 U.S.P.Q.2d 1438, 1442 (Fed. Cir. 1991). Fourth, if an obviousness rejection is based on some combination of prior art references, the Office must show a suggestion, teaching, or motivation to combine the prior art references ("the TSM test"). *In re Dembiczak,* 50 U.S.P.Q.2d 1614, 1617 (Fed. Cir. 1999). Following *KSR Int'l Co. v. Teleflex, Inc.*, this fourth prong of the *prima facie* obviousness analysis must not be applied in a rigid or formulaic way such that it becomes inconsistent with the more flexible approach of *Graham v. John Deere*, 383 U.S. 1, 17-18 (1966); 127 S. Ct. 1727 (2007). It must still be applied, however, as the TSM test captures the important insight that "a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." *Id.* at 1741 (citing *United States v. Adams*,

383 U.S. 39, 50-52 (1966)). The Appellants respectfully assert that the cited references fail to teach or suggest all the claim limitations.

Claims 17-25 and 28-38 were rejected under 35 U.S.C. 103(a) as being unpatentable over Fearnot et al. (Fearnot) in view of Hossainy et al. (Hossainy). Appellant respectfully points out that claims 22-24, 32-34 and 36 were previously canceled and, therefore, cannot be the subject of this rejection. In addition, the Examiner in the text of his rejection also refers to claims 40, 41, 43-45 and 47. Accordingly, Appellants will assume for purposes of this Appeal Brief that all pending and not withdrawn claims have been rejected over Fearnot in view of Hossainy. Appellants respectfully traverse this ground of rejection.

The cited references, even when combined, do not teach or suggest all of the limitations of the pending claims as currently amended. In particular they do not teach or suggest:

(a) a drug-polymer coated stent, comprising:

a stent framework; a laminated drug-polymer coating disposed on the stent framework, the laminated drug-polymer coating including a plurality of thin drug-polymer layers, wherein the thin drug-polymer layers include a first therapeutic agent and a cured first polymer, and

at least one thin barrier layer positioned between a first thin drug-polymer layer and a second thin drug-polymer layer, wherein the at least one thin barrier layer includes a cured second polymer, wherein the cured second polymer excludes drug interaction between the first thin drug-polymer layer and the second thin drug-polymer layer adjacent the at least one barrier layer, as in claim 17,

(b) a system for treating a vascular condition, comprising:

a catheter; and a coated stent coupled to the catheter, the coated stent including a stent framework and a laminated drug-polymer coating disposed on the stent framework, the laminated drug-polymer coating including a plurality of thin drug-polymer layers and at least one thin barrier layer positioned between a first thin drug-polymer layer and a second thin drug-polymer layer , wherein the thin drug-polymer layers include a first therapeutic agent and a cured first polymer and wherein the at least one thin barrier layer includes a cured second polymer, wherein the cured second polymer excludes drug interaction between the first thin drug-polymer layer and the second thin drug-polymer layer adjacent the at least one barrier layer, as in claim 25, or

(c) a method of treating a vascular condition, comprising:

inserting a drug-polymer coated stent within a vessel of a body, the drug-polymer coated stent including a laminated drug-polymer coating having a plurality of thin drug-polymer layers and at least one thin barrier layer positioned between a first thin drug-polymer layer and a second thin drug-polymer layer one, wherein the thin drug-polymer layers include a first therapeutic agent and a cured first polymer and wherein the at least one thin barrier layer includes a cured second polymer, wherein the cured second polymer excludes drug interaction between the first thin drug-polymer layer and the second thin drug-polymer layer adjacent the at least one barrier layer; and eluting at least one therapeutic agent from the laminated drug-polymer coating into the body, wherein the first polymer is cured with one of thermal activation, electrical activation, or ionizing irradiation, as in claim 35.

Most specifically, Fearnot does not teach at least one thin barrier layer positioned between a first thin drug-polymer layer and a second thin drug-polymer layer, wherein the thin drug-polymer layers include a first therapeutic agent and a cured first polymer and wherein the at least one thin barrier layer includes a cured second polymer, wherein the cured second polymer excludes drug interaction between

the first thin drug-polymer layer and the second thin drug-polymer layer adjacent the at least one barrier layer as recited in claims 17, 25 and 35.

At most, Fearnot teaches a method of coating a medical device surface by dipping the device into a solution containing a thrombolytic agent, allowing the solution to dry and repeating the dipping and drying, if necessary, to obtain the desired concentration or quantity of the thrombolytic agent on the device surface. Nowhere within the cited portions, or the entirety of the Fearnot patent, does the Fearnot patent teach or fairly suggest that any of the layers of the multi-layer coating is a barrier layer having a cured second polymer, wherein the cured second polymer excludes drug interaction between adjacent thin drug-polymer layers as claimed and described by the Appellants.

The Examiner has stated that "Fearnot further discloses thin diffusion barrier layers positioned between one or more thin drug-polymer layers, wherein the thin barrier layer includes a second polymer and a second therapeutic agent shown in figure 5 and described in column 2 on lines 10-25 of Fearnot." The Examiner has also stated that "it does not matter what the applicant or Fearnot calls the layers. Fearnot discloses a plurality of layers that are stacked up. Because of this stacking the upper layer will be exposed and released prior to the exposure of the inner layer. Therefore because of the structure and its method of manufacturing each outer layer of the device will act as a temporary, albeit short barrier layer." (See, Advisory Action mailed September 25, 2009). Appellants respectfully disagree to these Examiner assertions.

Figure 5 of Fearnot illustrates a medical device that has "three separate layers of antithrombogenic agent 14 and three separate layers of thrombolytic agent 13 applied thereover." (Fearnot, column 3, lines 47-50). Nowhere does Fearnot disclose that any of these layers are barrier layers as defined and claimed by the Appellant. Nor does Fearnot disclose that any such barrier layer, even if it did exist, includes a second polymer. If Appellants understand the Examiner's position correctly, he is implying, for example, that if there are three layers of a polymer

containing a drug, that somehow the middle layer acts as a barrier layer between the first and third layers. Aside from being pure speculation, this is not borne out in fact. It is well known in the drug-eluting stent manufacturing art that in order to obtain a suitably thick drug-polymer coating, multiple "layers" of drug and polymer must be applied. This is done by spraying, or similar method, of a solution of drug and polymer in a solvent. Application of each subsequent "layer" to the underlying one results in the solvent dissolving the surface of the underlying layer. The result is that there is eventually one thick coating, not a series of discernible thin layers. Thus, for example, in Figure 5 of Fearnot, even though three layers each of a polymer containing an antithrombogenic agent and a thrombolytic agent, respectively, are illustrated, that merely describes the process by which they are applied, not what an examination of the medical device would reveal. In fact, there would be only two true layers, one containing antithrombogenic agent in a polymer and another, over the first, containing thrombolytic agent in a polymer. Accordingly, there can be no "thin barrier layer positioned between a first thin drug-polymer layer and second thin drug-polymer layer" as required by the instant claims.

The Examiner has used Hossainy to purportedly cure the defects in Fearnot and for the proposition that "Hossainy also discloses the use of barrier layers between drug polymer layers to limit and control the release and interaction of the drug polymers." Appellants respectfully disagree. Hossainy merely discloses the use of a so-called "barrier layer" over a reservoir region. Hossainy at paragraph [0014] states "[T]he prosthesis can additionally include a barrier region disposed on a selected portion of the reservoir region for reducing the rate at which the active ingredient is released." In other words, Hossainy is merely describing a "capcoat," an outer coating used to protect a drug-containing layer and to control the elution of drug therefrom, and does not describe or suggest the use of a barrier layer between drug polymer layers as stated by the Examiner and as required by the claims. Furthermore, Hossainy does not describe or suggest that his barrier layer be of a second polymer as required by the instant claims.

In fact, Hossainy teaches away from this proposition. Hossainy, at paragraph [0070], when referring to the choice of polymer for the reservoir layer and the barrier (capcoat) layer, specifically states "[T]he use of the same polymer…significantly reduces or eliminates any interfacial incompatibilities, such as lack of adhesion, which may exist in the employment of two different polymeric layers." Hossainy goes on to state "in other words, the use of the same polymeric material results in a seamless multi-layered coating in which the layers vary in terms of their content. Defined interfacial boundaries are, accordingly, significantly reduced or eliminated." Accordingly, there would be no reason to combine the teachings of Hossainy with those of Fearnot, as the Examiner has done, to arrive at Appellants' invention. The Examiner is respectfully requested to withdraw the Section 103 rejection over Fearnot in view of Hossainy.

Claims 26 and 27 have been rejected under 35 U.S.C. 103 as being unpatentable over Fearnot in view of Hossainy and further in view of Guruwaiya et al. (Guruwaiya). Appellants respectfully traverse.

Claims 26 and 27 have been included in the discussion above with respect to the Section 103 rejection over Fearnot in view of Hossainy. Guruwaiya does not cure the defects thereof. Accordingly, Appellants maintain that these claims are patentable over Fearnot in view of Hossainy and further in view of Guruwaiya. The Examiner is respectfully requested to withdraw this rejection of Claims 26 and 27.

Claims 42 and 46 have been rejected under 35 U.S.C. 103 as being unpatentable over Fearnot in view of Hossainy and further in view of Helmus et al. (Helmus). Appellants respectfully traverse.

Claims 42 and 46 have been included in the discussion above with respect to the Section 103 rejection over Fearnot in view of Hossainy. Helmus does not cure the defects thereof. Accordingly, Appellants maintain that these claims are patentable over Fearnot in view of Hossainy and further in view of Helmus. The Examiner is respectfully requested to withdraw this rejection of Claims 42 and 46.

8. SUMMARY

The Appellants respectfully submit that claims 17-21, 25-31, 35, 37, 38 and 40-47 fully satisfy the requirements of 35 U.S.C. §103. In view of the foregoing, reversal of the rejection of claims 17-21, 25-31, 35, 37, 38 and 40-47 is respectfully requested.

Respectfully submitted,

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9. CLAIMS APPENDIX

Claim 1 (withdrawn): A method of applying a drug-polymer coating on a stent, comprising:

dipping a stent framework into a first polymeric solution, wherein the first polymeric solution comprises a first polymer, a first therapeutic agent, and a first solvent;

forming a thin drug-polymer layer on the stent framework, wherein the first polymeric solution is dried and wherein the first polymer is cured; and

repeating the steps of dipping the stent framework into the first polymeric solution and forming the thin drug-polymer layer until a target thickness of the drug-polymer coating with the thin drug-polymer layers is disposed on the stent framework.

Claim 2 (withdrawn): The method of claim 1 wherein the first polymeric solution comprises a first polymer including a low molecular weight silicone oil, a cross-linking agent, and a catalyst.

Claim 3 (withdrawn): The method of claim 2 wherein the cross-linking agent comprises tetrapropylorthosilicate.

Claim 4 (withdrawn): The method of claim 2 wherein the catalyst comprises stannous octoate.

Claim 5 (withdrawn): The method of claim 1 wherein the first polymeric solution comprises a first monomer including poly acrylic acid, a second monomer including vinyl pyrollidone, and an initiator.

Claim 6 (withdrawn): The method of claim 5 wherein the initiator comprises benzophenone.

Claim 7 (withdrawn): The method of claim 1 wherein the first polymeric solution comprises between 0.05 percent and 3.0 percent total solids by weight of the first polymer.

Claim 8 (withdrawn): The method of claim 1 wherein the first therapeutic agent is selected from the group consisting of rapamycin, a rapamycin derivative, a rapamycin analogue, camptothecin, dexamethasone, 5-fluorouracil, a bioactive agent, a pharmaceutical drug, a therapeutic substance, and a combination thereof.

Claim 9 (withdrawn): The method of claim 1 wherein forming the thin drug-polymer layer comprises drying the first polymeric solution and curing the first polymer with ultraviolet light.

Claim 10 (withdrawn): The method of claim 1 wherein forming the thin drug-polymer layer comprises drying the first polymeric solution and curing the first polymer with one of thermal activation, electrical activation, or ionizing irradiation.

Claim 11 (withdrawn): The method of claim 1 further comprising:

adding an ultraviolet-sensitive catalyst into the first polymeric solution prior to dipping the stent framework into the first polymeric solution.

Claim 12 (withdrawn): The method of claim 1 further comprising:

adding one of an initiator or a crosslinking agent into the first polymeric solution prior to dipping the stent framework into the first polymeric solution.

Claim 13 (withdrawn): The method of claim 1 further comprising:

dipping the stent framework including the formed thin drug-polymer layer into a second polymeric solution, wherein the second polymeric solution comprises a second polymer and a second solvent;

forming a thin barrier layer on the formed thin drug-polymer layer, wherein the second polymeric solution is dried and wherein the second polymer is cured; and

repeating the steps of dipping the stent framework into the first polymeric solution and forming an additional thin drug-polymer layer, and dipping the stent framework including the additional thin drug-polymer layer and forming the thin barrier on the thin drug polymer layer, until a target thickness of the drug-polymer coating with the thin drug-polymer layers and the thin barrier layers is disposed on the stent framework.

Claim 14 (withdrawn): The method of claim 13 wherein the second polymeric solution comprises a second therapeutic agent.

Claim 15 (withdrawn): The method of claim 14 wherein the second therapeutic agent is selected from the group consisting of rapamycin, a rapamycin derivative, a rapamycin analogue, camptothecin, dexamethasone, 5-fluorouracil, a bioactive agent, a pharmaceutical drug, a therapeutic substance, and a combination thereof.

Claim 16 (withdrawn): The method of claim 1 further comprising:

modulating a concentration of the first therapeutic agent in the thin drug-polymer layers to provide a predetermined drug-release profile.

Claim 17 (previously presented): A drug-polymer coated stent, comprising:

a stent framework;

a laminated drug-polymer coating disposed on the stent framework, the laminated drug-polymer coating including a plurality of thin drug-polymer layers, wherein the thin drug-polymer layers include a first therapeutic agent and a cured first polymer, and

at least one thin barrier layer positioned between a first thin drug-polymer layer and a second thin drug-polymer layer, wherein the at least one thin barrier layer includes a cured second polymer, wherein the cured second polymer excludes drug interaction between the first thin drug-polymer layer and the second thin drug-polymer layer adjacent the at least one barrier layer.

Claim 18 (original): The stent of claim 17 wherein the stent framework comprises one of a metallic base or a polymeric base.

Claim 19 (original): The stent of claim 17 wherein the stent framework comprises a material selected from the group consisting of stainless steel, nitinol, tantalum, MP35N alloy, platinum, titanium, a chromium-based alloy, a suitable biocompatible alloy, a suitable biocompatible material, a biocompatible polymer, and a combination thereof.

Claim 20 (original): The stent of claim 17 wherein the first therapeutic agent is selected from the group consisting of rapamycin, a rapamycin derivative, a rapamycin analogue, camptothecin, dexamethasone, 5-fluorouracil, a bioactive agent, a pharmaceutical drug, a therapeutic substance, and a combination thereof.

Claim 21 (original): The stent of claim 17, wherein a concentration of the first therapeutic agent is modulated to provide a predetermined drug-release profile.

Claims 22-24 (cancelled):

Claim 25 (previously presented): A system for treating a vascular condition, comprising:

a catheter; and

a coated stent coupled to the catheter, the coated stent including a stent framework and a laminated drug-polymer coating disposed on the stent framework, the laminated drug-polymer coating including a plurality of thin drug-polymer layers and at least one thin barrier layer positioned between a first thin drug-polymer layer and a second thin drug-polymer layer ,

wherein the thin drug-polymer layers include a first therapeutic agent and a cured first polymer and wherein the at least one thin barrier layer includes a cured second polymer, wherein the cured second polymer excludes drug interaction between the first thin drug-polymer layer and the second thin drug-polymer layer adjacent the at least one barrier layer.

Claim 26 (original): The system of claim 25 wherein the catheter includes a balloon to expand the stent.

Claim 27 (original): The system of claim 25, wherein the catheter includes a sheath that retracts to allow expansion of the stent.

Claim 28 (original): The system of claim 25 wherein the stent framework comprises one of a metallic base or a polymeric base.

Claim 29 (original): The system of claim 25 wherein the stent framework comprises a material selected from the group consisting of stainless steel, nitinol, tantalum, MP35N alloy, platinum, titanium, a chromium-based alloy, a

suitable biocompatible alloy, a suitable biocompatible material, a biocompatible polymer, and a combination thereof.

Claim 30 (original): The system of claim 25 wherein the first therapeutic agent is selected from the group consisting of rapamycin, a rapamycin derivative, a rapamycin analogue, camptothecin, dexamethasone, 5-fluorouracil, a bioactive agent, a pharmaceutical drug, a therapeutic substance, and a combination thereof.

Claim 31 (original): The system of claim 25 wherein a concentration of the first therapeutic agent is modulated to provide a predetermined drug-release profile.

Claims 32-34 (cancelled):

Claim 35 (previously presented): A method of treating a vascular condition, comprising:

inserting a drug-polymer coated stent within a vessel of a body, the drug-polymer coated stent including a laminated drug-polymer coating having a plurality of thin drug-polymer layers and at least one thin barrier layer positioned between a first thin drug-polymer layer and a second thin drug-polymer layer one, wherein the thin drug-polymer layers include a first therapeutic agent and a cured first polymer and wherein the at least one thin barrier layer includes a cured second polymer, wherein the cured second polymer excludes drug interaction between the

first thin drug-polymer layer and the second thin drug-polymer layer adjacent the at least one barrier layer; and

eluting at least one therapeutic agent from the laminated drug-polymer coating into the body,

wherein the first polymer is cured with one of thermal activation, electrical activation, or ionizing irradiation.

Claim 36 (cancelled)

Claim 37 (previously presented): The method of claim 35 wherein the thin barrier layers control an elution rate of at least one therapeutic agent.

Claim 38 (previously presented): The method of claim 35 further comprising:

selecting the cured first polymer and the cured second polymer based on a predetermined elution rate of at least one therapeutic agent.

Claim 39 (cancelled)

Claim 40 (previously presented): The stent of claim 17 wherein the at least one thin barrier layer comprises a diffusion barrier.

Claim 41 (previously presented): The stent of claim 17 wherein the cured second polymer comprises a silicone polymer.

Claim 42 (previously presented): The stent of claim 17 wherein the cured second polymer comprises an amphiphilic copolymer from acrylic acid and vinyl pyrollidone.

Claim 43 (previously presented): The stent of claim 17 further comprising a primer coat disposed directly on an outer surface of the stent framework.

Claim 44 (previously presented): The system of claim 25 wherein the at least one thin barrier layer comprises a diffusion barrier.

Claim 45 (previously presented): The system of claim 25 wherein the cured second polymer comprises a silicone polymer.

Claim 46 (previously presented): The system of claim 25 wherein the cured second polymer comprises an amphiphilic copolymer from acrylic acid and vinyl pyrollidone.

Claim 47 (previously presented): The method of claim 35 wherein the at least one thin barrier layer comprises a diffusion barrier.

10. EVIDENCE APPENDIX

None.

11. RELATED PROCEEDINGS APPENDIX

None.